SensiLase™ PAD 3000

Skin Perfusion Pressure System

Operators Manual

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Covered by one or more of the following U.S. Patents and foreign equivalents: 4,596,254; 4,772,081; 5,654,539; and 6,178,342.

Caution – Federal law (USA) restricts this device to sale by or on the order of a physician.

To contact a **väsamed** representative, call 1.800.695.2737.

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Introduction

SensiLase™ PAD 3000 System

The **väsamed** SensiLase PAD 3000 System (SensiLase System) performs skin perfusion pressure (SPP) and pulse volume recording (PVR) tests. The system consists of the following components:

- SensiLase Data Acquisition System (DAS)
- Personal Computer (PC) with SensiLase Application Software
- SensiLase Laser Sensor Assembly (LSA)
- Pressure Cuffs
- Air Hose
- Data Port Cable
- Power Cable (DAS to PC)
- DAS AC Power Cord
- Roll Stand (optional)

Indications for Use

The SensiLase PAD 3000 System provides a noninvasive measurement of skin perfusion pressure (SPP) and pulse volume recording (PVR) waveforms on extremities of patients.

It is indicated for use on hospital and clinic patients.

This system is indicated for use by qualified medical personnel only.

The SensiLase System is to be used only with the SensiLase Laser Sensor Assembly (LSA).

Contraindications

There are no known contraindications for the SensiLase System.

Principles of Operation

Skin Perfusion Pressure (SPP)

The Skin Perfusion Pressure (SPP) test provides a fully automated and quantitative evaluation of microcirculatory perfusion in the skin. The SPP test measures skin perfusion using a laser Doppler sensor (the Laser Sensor Assembly) located beneath a pressure cuff for application and release of pressure to the limb. During an SPP test, the pressure cuff is first automatically inflated until the LSA determines that perfusion beneath the cuff has stopped. The pressure is then automatically released at a controlled rate while the cuff pressure and skin perfusion are measured. A graph displays pressure and perfusion during cuff deflation and indicates the pressure at which skin perfusion is found to return. The SPP test generally takes less than five minutes to complete.

The SPP test can be useful in identifying patients with peripheral arterial disease (PAD) and other alterations in microcirculation. The SPP test can also be used as an aid in the determination of optimum clinical treatment for patients with intractable wounds. Patients with chronic foot ulcers, diabetics, and candidates for amputation often have serious alterations in circulation. Clinical studies have demonstrated that the SPP test is not affected by edema, anemia or medial calcification.

Pulse Volume Recording (PVR)

The Pulse Volume Recording (PVR) test measures and displays a waveform that represents variations in the size of a limb when blood passes through it during each cardiac cycle. The PVR test is fully automated. The PVR test uses a partially inflated pressure cuff to apply slight pressure to the limb. The impact of blood passing through the limb is transferred to the pressure cuff where it is measured as small changes in cuff pressure and displayed as a PVR waveform. A user may elect to stop the PVR test when a satisfactory waveform is available, usually about thirty seconds after starting, or wait for the test to timeout in five minutes. The PVR test is sometimes referred to as air plethysmography.

The PVR test can be useful in providing an indication of peripheral arterial disease (PAD) and other alterations in macrocirculation. The PVR test can also be used as an aid in the determination of optimum clinical treatment. Examination of the amplitude, frequency, and pulse contours allow an interpretation of intraluminal changes in connection with occlusive disease. The PVR waveform can be used as a measure of the functional severity of the occlusive disease as well as an objective baseline for later comparisons.

Safety Information

This section contains important safety information related to the general use of the SensiLase PAD 3000 System (SensiLase System). Other important safety information appears throughout the manual in sections that relate specifically to the precautionary information. Be sure to read all text surrounding all precautionary information.

Before use, carefully read this manual, the accessory directions for use and all warnings, cautions, notes, as well as all specifications.

Warnings and cautions are identified by the symbol shown above. A warning designates a possible dangerous situation. Non-observance may lead to death or injuries. A caution designates a possibly harmful situation. Non-observance may lead to damage to the product or the environment.

Warnings

- **The SensiLase System (DAS connected to väsamed supplied PC) complies with IEC 60601-1-1. The PC is powered through the DAS and the system uses a common power cable. The väsamed supplied PC is IEC 60950-1 compliant. If a printer is connected to the SensiLase System it will not be able to use the common power cable and this is a violation of constructional requirements of IEC 60601-1-1. A simple way to conveniently adhere to IEC 60601-1-1 regulation is to defer printing results until patient testing is complete and the LSA and cuff are removed from the patient. At that point, assure that the printer is 1.5 meters away from the patient. For additional information or for information that will assist your institution to comply with IEC 606010101, please contact väsamed Customer Service at 800-695-2737.**

- **This product emits invisible laser radiation from the distal end of the LSA and is designated a Class 1M laser product per IEC60825-1. Do not view laser light directly with optical instruments such as eye loupes, magnifiers or microscopes. Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.**

- **To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.**

- **This equipment has been tested and found to comply with the limits for medical devices to IEC 601-1-2:2001. This testing shows the device provides reasonable protection against harmful interference in a typical medical installation.**

However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices or is negatively impacted by other devices, the user is encouraged to try to correct the interference by one or more of the following measures:

- **Reorient or relocate the devices.**
- **Increase the separation between the devices.**
- **Connect the equipment to an outlet on a different circuit.**
- **Consult the manufacturer or field service technician for help.**

- **The SensiLase DAS must be powered with the väsamed supplied AC power cord or with a replacement AC power cord that meets the same requirements.**

- **The SensiLase System is designed for the supplied personal computer (PC) to receive power from the SensiLase DAS. The PC must be connected to the DAS with the väsamed supplied power cable. Do not use other power cords or cables to power the PC.**

- **If the väsamed-supplied PC will not be used for two (2) months or longer, remove the PC battery pack prior to storage.**

- **If the equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.**

- **When using the SensiLase System in the patient environment, do not connect any items, such as other cables or devices, to the SensiLase System that are not specified components of the system.**

- **Explosion hazard. Do not use the SensiLase System in the presence of flammable anesthetics or gases.**

- **In the event fluids are accidentally spilled on the equipment, take the equipment out of service and contact väsamed service personnel.**

- **For continued safe use of this equipment, it is necessary that the listed instructions be followed. However, instructions listed in this manual in no way supersede established medical procedures concerning patient care.**

- **Contact väsamed service personnel if service of the SensiLase System is required. No service should be attempted by anyone other than authorized personnel.**

- **Do not kink or crush the LSA cable or Air Hose. A damaged cable or air hose can result in inaccurate values or an error message.**

- **To maintain proper ventilation and ensure proper cooling, place the DAS on a hard, flat surface with a minimum of 1-inch (2.5 cm) clearance around all sides of the DAS. Do not set the DAS on bedding.**

Cautions

- **Federal law (USA) restricts this device to sale by or on the order of a physician.**
- **The cover of the DAS should be removed only by authorized väsamed service personnel. There are no user-serviceable parts inside the DAS.**
- **The patient should be supine and lying completely still during SPP or PVR tests. Stay with the patient during the SPP or PVR test. Any type of patient movement, including talking, may result in incorrect or no results being displayed or cause the system to time out. Results may also be affected by movement of the Laser Sensor Assembly cable or the Air Hose.**
- **When performing an SPP measurement, do not place LSA directly over a bone.**
- **Do not wrap the pressure cuff around the extremity too tightly. Blood flow may be restricted. Wrap the pressure cuff snugly, but not tightly, around the patient's extremity.**
- **väsamed is not responsible if the DAS is connected to a computer that does not comply with medical safety regulations. The DAS and computer must have a combined leakage current less than 0.1 mA and be compatible with applicable medical safety regulations.**
- **If the SensiLase DAS or other system components are stored outside the operating temperature range (5° to 40° C), make sure the DAS or components return to operating temperature before use.**
- **Before use, check the DAS and all components for signs of wear and fatigue.**
- **Do not set items on top of the laptop PC, the screen may become damaged.**

Notes

Notes are listed before or after procedural steps or instructions and provide additional guidelines or information on the subject described.

SensiLase PAD 3000 System

Product Description and Components

The **väsamed** SensiLase PAD 3000 System (SensiLase System) performs skin perfusion pressure (SPP) and pulse volume recording (PVR) tests. See Figure 1 for a system diagram. The system consists of the following components listed below. A brief description of each component is provided.

SensiLase Data Acquisition System (DAS) – The DAS interfaces to the SensiLase Laser Sensor Assembly (LSA) and Pressure Cuffs and performs control and signal processing. Communication between the DAS and PC is accomplished through the Data Port Cable

Personal Computer (PC) with SensiLase Application Software – The PC runs on a Windows® based operating system. SensiLase Application Software provides the user interface, displays SPP and PVR test results, stores patient data, and generates patient reports.

SensiLase Laser Sensor Assembly (LSA) – The reusable, fiber optic LSA consists of a connector, cable, and SPP sensor (Figure 4). The LSA connects to the DAS and allows for testing of SPP.

Pressure Cuffs – Three pressure cuff sizes are available for performing SPP and PVR tests (Figure 4). The medium cuff is used on the leg, the small cuff on the foot or ankle, and the micro cuff on the digits. The cuff applies pressure to the area being tested. The cuff extender attaches to the medium cuff when a longer cuff is needed for the leg.

Air Hose – The Air Hose (Figure 4) connects the pressure cuff to the DAS and allows the DAS to control cuff pressure.

Data Port Cable – The Data Port Cable connects the DAS to the PC and allows for communication between the DAS and PC.

Power Cable – The power cable connects the DAS to the PC and supplies electrical power from the DAS to the PC.

AC Power Cord – The AC power cord supplies power to the DAS. It connects to the DAS and a standard electrical outlet.

Note

- Replacement components and accessories are available through **väsamed**.

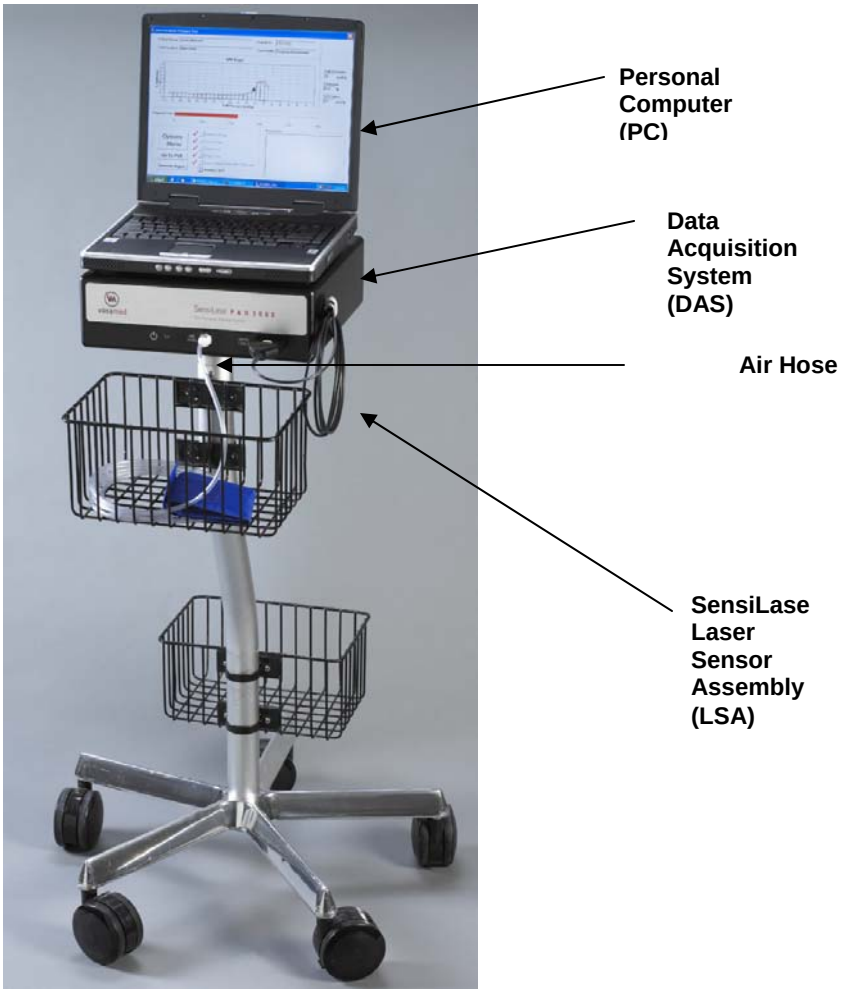


Figure 1. SensiLase PAD 3000 System

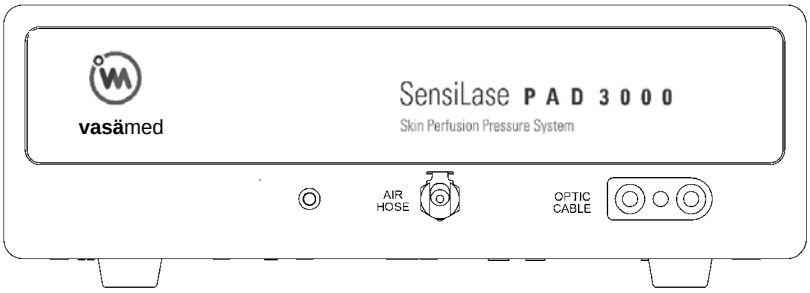


Figure 2. DAS Front Panel

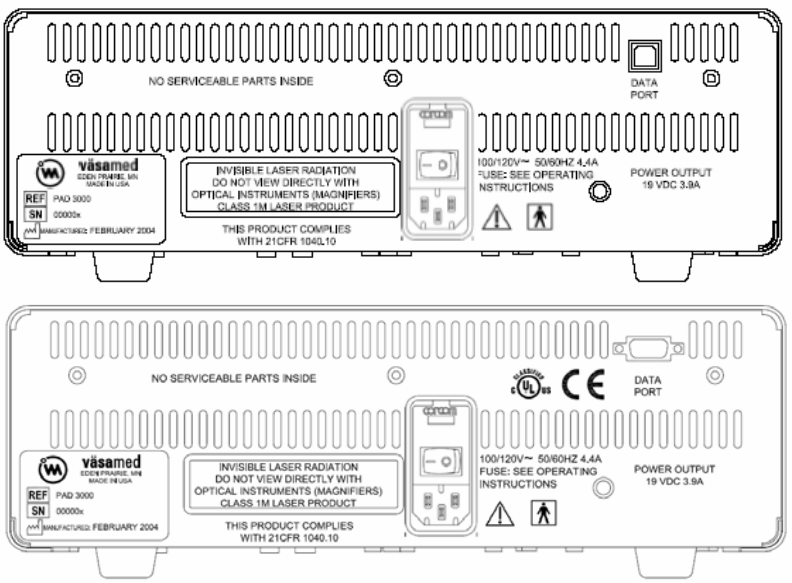


Figure 3. DAS Back Panel

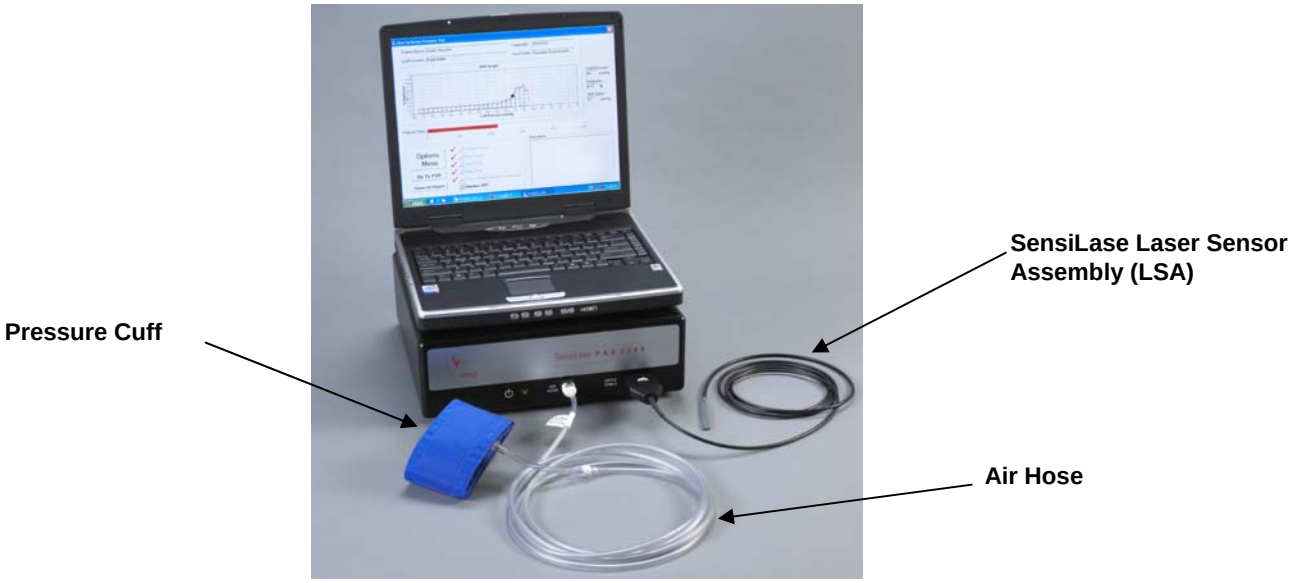


Figure 4. Accessories

Setting up the SensiLase PAD 3000 System

- **Warning: To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.**

- **Warning: The SensiLase DAS must be powered with the väsamed supplied AC power cord or with a replacement AC power cord that meets the same requirements.**

- **Warning: The SensiLase System is designed for the supplied personal computer (PC) to receive power from the SensiLase DAS. The PC must be connected to the DAS with the väsamed supplied power cable. Do not use other power cords or cables to power the PC.**

- **Warning: When using the SensiLase System in the patient environment, do not connect any items, such as other cables or devices, to the SensiLase System that are not specified components of the system.**

- **Warning: Do not kink or crush the LSA cable or Air Hose. A damaged cable or hose can result in inaccurate values or an error message.**

- **Warning: To maintain proper ventilation and ensure proper cooling, place the DAS on a hard, flat surface with a minimum of 1-inch (2.5 cm) clearance around all sides of the DAS. Do not set the DAS on bedding.**

- **Caution: väsamed is not responsible if the DAS is connected to a computer that does not comply with medical safety regulations. The DAS and computer must have a combined leakage current less than 0.1 mA and be compatible with applicable medical safety regulations.**

- **Caution: If the SensiLase DAS or other system components are stored outside the operating temperature range (5° to 40° C), make sure the DAS or components return to operating temperature before use.**

Equipment Setup

Have the following equipment available before beginning equipment setup:

- SensiLase Data Acquisition System (DAS)
- Personal Computer (PC) with SensiLase Application Software
- SensiLase Laser Sensor Assembly (LSA)
- Pressure Cuffs
- Air Hose
- Data Port Cable
- Power Cable (DAS to PC)
- DAS AC Power Cord

Follow the steps below to set up the hardware components of the SensiLase System. If you purchased DAS only, please see "Customer Supplied Computer Minimum Requirements".

1. Place the DAS and PC on a stable surface or secure to the optional roll-stand (Figure 1). An appropriate roll-stand may be obtained from **väsamed**. (See instructions below for securing the DAS to the roll-stand and for securing the DAS to the väsamed-supplied PC.)
2. Connect the square end of the Data Port Cable to the back of the DAS (Figure 3) at the Data Port connector.
3. Connect the rectangular end of the Data Port Cable to the PC.
4. Connect the power cable to the DAS and the PC.
5. Connect the LSA connector to the front of the DAS (Figure 2) at the Optical Cable connector. Push the connector into the DAS and tighten the thumbscrew.
6. Connect the Air Hose to the front of the DAS (Figure 2) at the Air Hose connector. Push the o-ring connector into the DAS. A click will be heard.
7. Connect the AC power cord to the DAS.
8. Insert the AC power cord plug into a standard electrical outlet.
9. Turn the SensiLase System on:
    a. Press the On/Off button on the back of the DAS.
    b. Press the On/Off button on the PC. The log in window and Skin Perfusion Pressure Test screen appear (Figure 7 and Figure 8).

Note

- The green power indicator on the DAS front panel blinks when the SensiLase System is first turned on and SPP view has not yet communicated with the DAS or when an error occurs.

Optional Roll Stand and PC Setup Instructions

Have the following equipment available before beginning:

- Large, flat head screw driver
- Four (4) mounting plate screws (these are in the plastic bag containing the Roll Stand Assembly and Operation Installation Guide),

1. To secure DAS to roll stand.

    a. To secure the DAS to the optional Roll Stand obtained from **väsamed**, you will first set up the Roll Stand according the instructions supplied in the Roll Stand shipping carton. These instructions (Assembly and Operation Installation Guide) are inside a clear plastic bag in the shipping carton. There are four (4) screws enclosed with the instructions. These will be used in Step c below. This custom Roll Stand from väsamed already has the Mounting Plate installed and attached to the Roll Stand Post. This Mounting Plate does not rotate. This custom Roll Stand does not have a Foot Pedal. Use the Roll Stand instructions for Attaching Roll Stand Post to Base. See Figure 5.

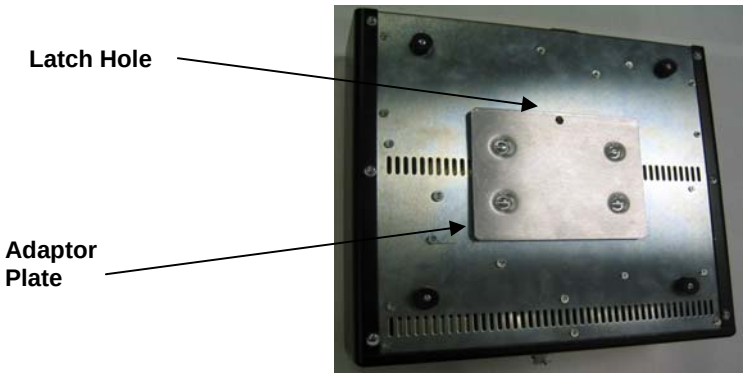


Figure 5 Bottom Panel of DAS

    b. Use the Roll Stand Instructions to identify the Roll Stand Mounting Plate at the top of the Post. The Adaptor Plate that you need to attach to the bottom of the DAS slides out from its location within the Mounting Plate. Remove the Adaptor Plate now.
    c. Position the Roll Stand Adaptor Plate with the latch hole located to the rear of the DAS and attach the Adaptor Plate to the bottom of the DAS using the four (4) screws.

d. Secure DAS to Roll Stand by sliding DAS-Adaptor Plate onto Mounting Plate. Make sure that the Stainless Steel Plunger Pin on the Mounting Plate is located to the rear of the DAS so it can lock into position in the latch hole
e. As the Adaptor Plate slides into place, pull the Stainless Steel Plunger Pin of the Mounting Plate so that the Adaptor Plate moves freely over the Pin.
f. Release the Pin and continue to slide the Adaptor Plate until the Pin automatically locks into the latch hole securing the DAS-Adaptor Plate in place.

2. To secure PC to DAS
    a. With the PC closed, position laptop so pre-positioned Velcro fasteners located on bottom of laptop match the Velcro fastener placement on top of DAS.
    b. Firmly press four corners of laptop to DAS until a snapping sound is heard.

Disconnecting the Air Hose and LSA from the DAS

To disconnect the Air Hose from the DAS:
1. Press down on the metal tab with your thumb and pull straight out.

To disconnect the LSA from the DAS:
1. Loosen the thumbscrew and pull straight out.

Quick Keys

The SensiLase System uses quick keys to allow the user to quickly select a function with one simple key stroke. Quick keys are either letters or numbers.

Letter quick keys are designated by an underlined letter in a word (e.g. Login). In the User Login window below (Figure 7), enter the letter **L** to login after the user name has been selected and password entered or enter the letter **E** to exit the program.

Numbers are also used as quick keys. For example, on the SPP and PVR screens, numbers are used to select various steps (Figure 6). At the beginning of the SPP test, enter the number **1** to begin the test and go to the Patient Setup window.

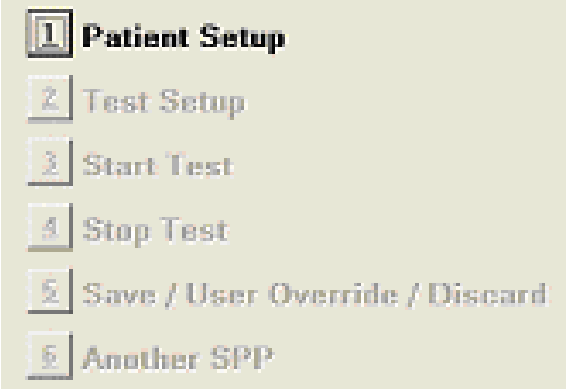


Figure 6. SPP Quick Keys

Login

Each user must login before using the SensiLase System. The login window (Figure 7) is displayed when the SensiLase System is powered on. To log in:

1. Use the drop down list under **User Name** to select your name.
2. Enter your **Password**.
3. Select **Login**. The Skin Perfusion Pressure Test screen is displayed (Figure 8).

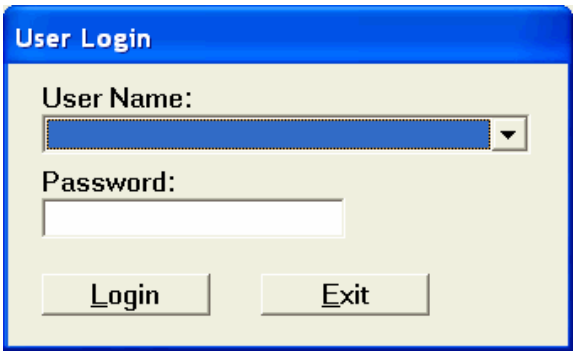


Figure 7. User Login Window

Skin Perfusion Pressure (SPP) Test

- **Warning: Do not kink or crush the LSA cable or Air Hose. A damaged cable or air hose can result in inaccurate values or an error message.**

- **Warning: To maintain proper ventilation and ensure proper cooling, place the DAS on a hard, flat surface with a minimum of 1-inch (2.5 cm) clearance around all sides of the DAS. Do not set the DAS on bedding.**

- **Caution: When performing an SPP measurement, do not place the LSA directly over a bone.**

- **Caution: Do not wrap the pressure cuff around the extremity too tightly. Blood flow may be restricted. Wrap the pressure cuff snugly, but not tightly, around the patient's extremity.**

- **Caution: The patient should be supine and lying completely still during SPP tests. Stay with the patient during the SPP test. Any type of patient movement, including talking, may result in incorrect or no results being displayed or cause the system to time out. Results may also be affected by movement of the Laser Sensor Assembly cable or the Air Hose.**

Performing a Skin Perfusion Pressure (SPP) Test

The Skin Perfusion Pressure (SPP) Test screen (Figure 8) is automatically displayed after turning the system on and logging in. An SPP test is performed by moving through the six steps listed on the SPP screen.

1 – Patient Setup
2 – Test Setup
3 – Start Test
4 – Stop Test (if needed)
5 – Save / Override / Discard
6 – Another SPP

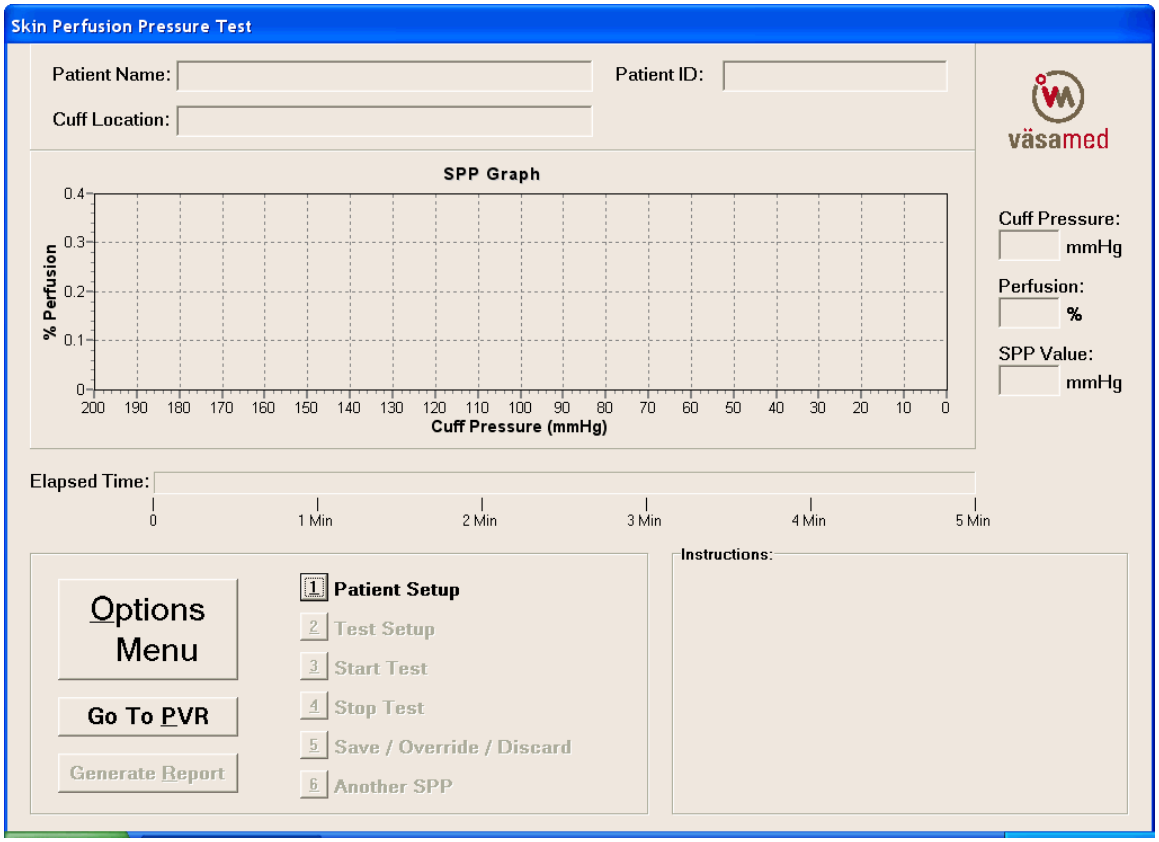


Figure 8 - Skin Perfusion Pressure Test Screen

1 – Patient Setup

Before performing an SPP test, the patient should lie quietly for 10 minutes. Have the patient lie in a comfortable, supine position.

1. To begin the SPP test, select **1-Patient Setup**. The **Patient Setup** window appears (Figure 9).
2. Make the appropriate selection under **Patient Selection**.

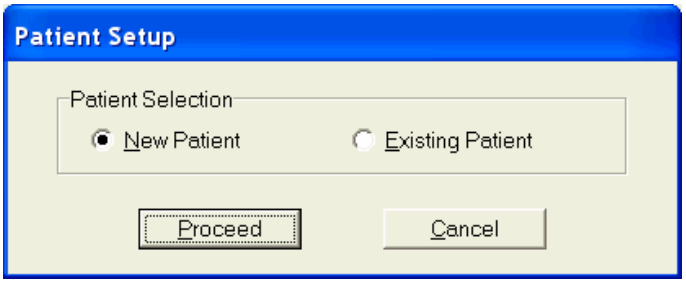


Figure 9. Patient Setup Window

New Patient

1. Select **New Patient** if the patient has not been tested before.
2. Select **Proceed**.
3. Enter the Patient ID number (Figure 10).
4. Select **Proceed** when the ID number is entered correctly to advance to the **Vascular History – Add or Modify Patient Data** form (Figure 11).

Note

- The patient identification number can include numbers, letters or a combination of both. Up to 20 characters may be entered.
- Additional patient information, including the patient's name, is entered on the Vascular History form.

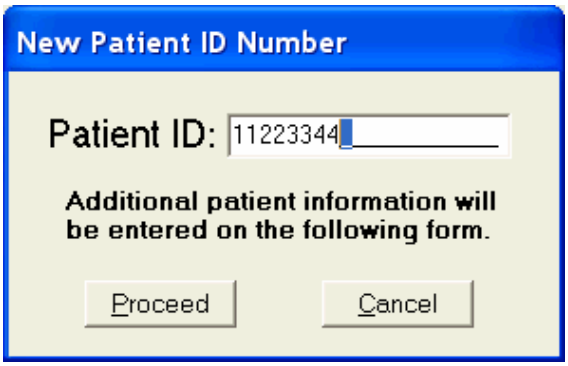


Figure 10. New Patient ID Number Window

Vascular History – Add or Modify Patient Data

At the **Vascular History** form:

1. Enter the patient's data.
2. Select **Proceed** when the patient's data is entered correctly. The SPP Test Screen is displayed.

Note

- The date of birth (DOB) must be entered in MM/DD/YYYY or MM/DD/YY format. (Example: 10/22/1938 or 10/22/38).

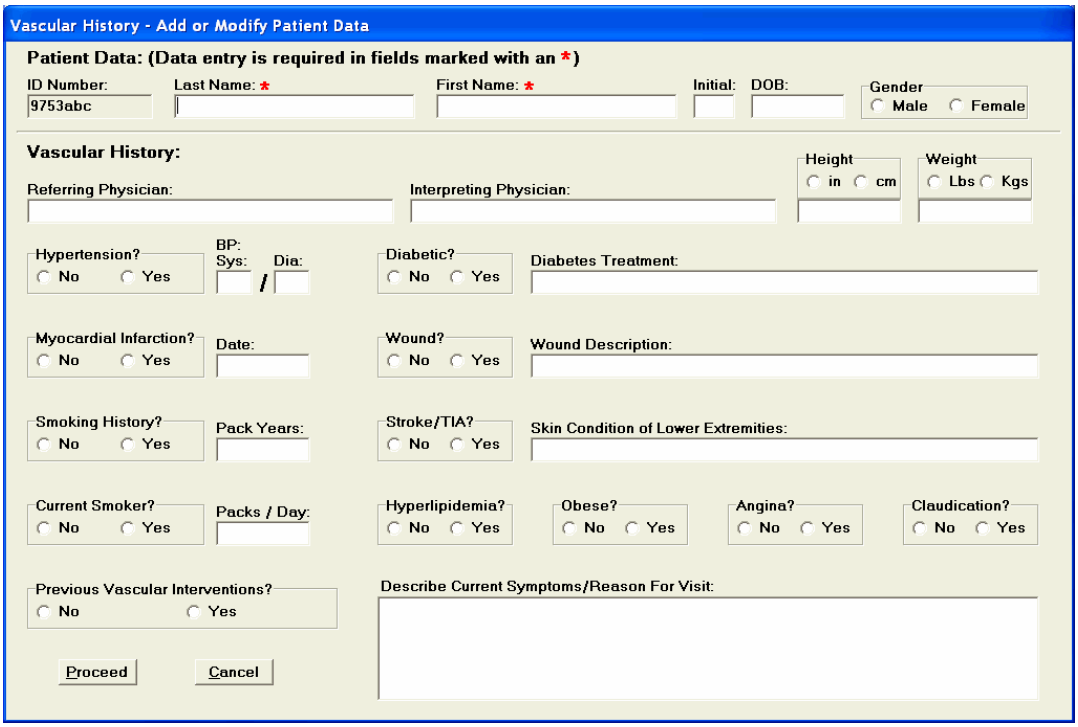


Figure 11. Vascular History – Add or Modify Patient Form

Existing Patient

1. Select **Existing Patient** if the patient has been tested before.
2. Select **Proceed**. The **Select Patient** screen appears (Figure 12).

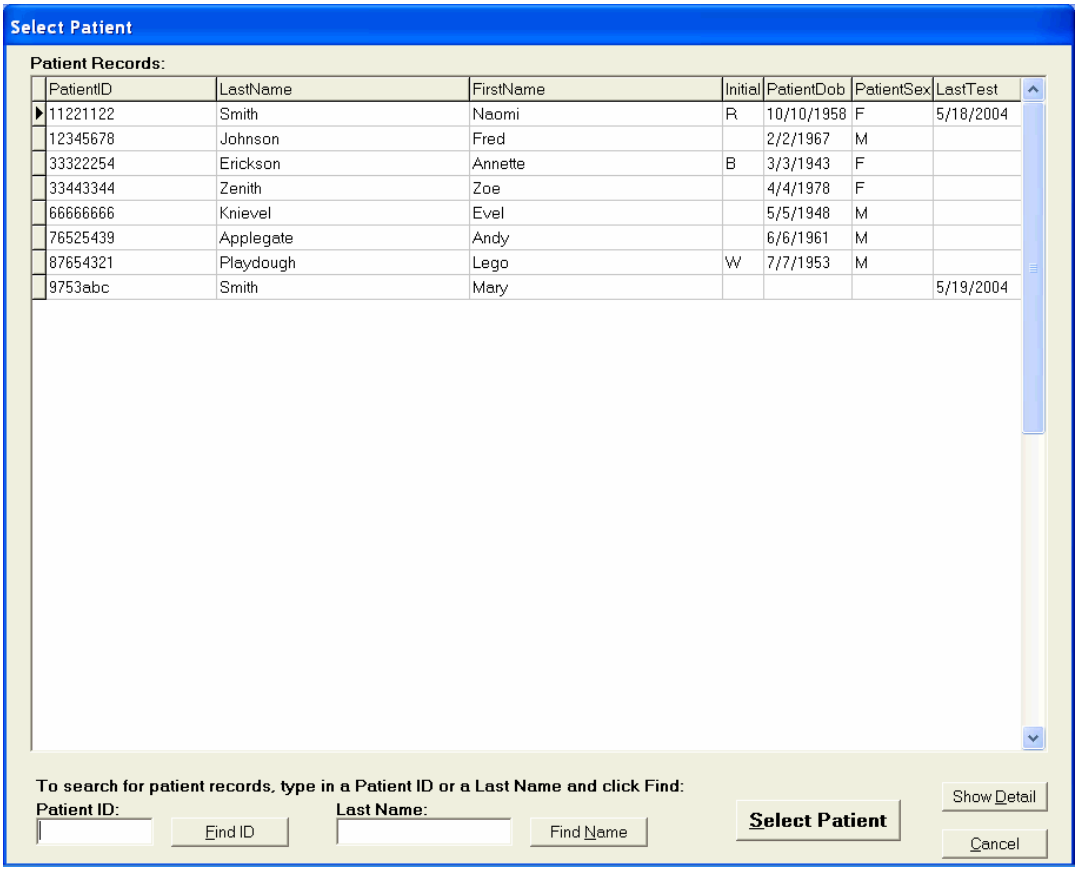

Select Patient
Patient Records:
PatientID LastName FirstName Initial PatientDob PatientSex LastTest
11221122 Smith Naomi R 10/10/1958 F 5/18/2004
12345678 Johnson Fred 2/2/1967 M
33322254 Erickson Annette B 3/3/1943 F
33443344 Zenith Zoe 4/4/1978 F
66666666 Knievel Evel 5/5/1948 M
76525439 Applegate Andy 6/6/1961 M
87654321 Playdough Lego W 7/7/1953 M
9753abc Smith Mary 5/19/2004
To search for patient records, type in a Patient ID or a Last Name and click Find:
Patient ID:
Find ID
Last Name:
Find Name
Select Patient
Show Detail
Cancel

Figure 12. Select Patient Screen

3. Choose one of the following ways to locate the correct patient.
   - Type in the patient's identification number in the **Patient ID** box at the bottom of the screen and then click **Find ID**.
   - Type in the patient's last name in the **Last Name** box at the bottom of the screen and then click **Find Name**.
   - Use the vertical scroll bar to the right of **Patient Records** and select row with desired patient record.
4. Select **Select Patient**.
5. Select **Yes** when you are sure of your selection. The Skin Perfusion Pressure Test screen appears.

Note

- Details of **Vascular History Records** and **Test Data Records** can be viewed by selecting **Show Detail** on the **Select Patient** screen (Figure 12).

2 – Test Setup

1. Select **2-Test Setup**. The **SPP Test Setup** form appears (Figure 13).

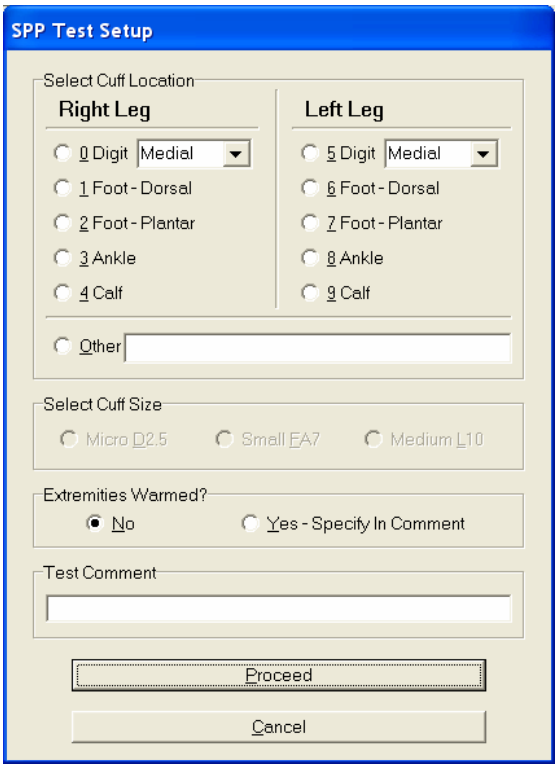


Figure 13. SPP Test Setup Form

At the **SPP Test Setup** form:

1. Select the appropriate **Cuff Location**. Only one location can be selected.
2. A default cuff size based on the Cuff Location is automatically selected. Change the cuff size if needed.
3. Under **Extremities Warmed?**, **No** is automatically selected as the default. If a warming pad or other extraordinary means of providing warmth is used to warm the extremity, select **Yes** and explain in the **Test Comments** box.

Note

- Any patient position other than supine may affect the results.
- Use the appropriate size pressure cuff for the location that you are testing. Using a pressure cuff that is too large or small may affect the test.
- The patient should be at their comfortable/normal body temperature as should the extremity to be tested. If this is not the case, the patient should be covered with a blanket at the discretion of the physician.
- Use of a warming pad is not recommended but if its use is elected at the discretion of the physician, it should be noted during test setup.

4. Connect the pressure cuff to the air hose with the Luer connector.
5. Place the LSA at the location SPP will be determined.
    - Ensure the metal sensor is oriented toward the patient's skin at the measurement site. The SensiLase name should be clearly visible. The sensor must be oriented correctly for SPP to be determined.
    - Ensure the LSA cable is oriented so the cable does not become entangled in the pressure cuff.
6. Place the pressure cuff over the sensor and wrap it snugly around the patient's extremity.
    - Ensure the center of the cuff is placed over the LSA.
12. Select P**roceed** at the bottom of the form when you are ready to start the SPP test. The Skin Perfusion Pressure Test screen is displayed and the **Start Test** button is activated and ready for selection.
13. Position the computer screen so the patient cannot see it.
14. Inform the patient that you are ready to start the test and that the cuff will apply pressure to the area being tested.

3 – Start Test

1. Select **3-Start Test** to begin the SPP test.

Note

- **Elapsed Time** indicates the SPP test is in progress.
- **Cuff Pressure** is displayed as the pressure cuff automatically inflates and deflates.
- As the SPP test progresses, an **SPP Graph** is displayed as the pressure cuff deflates (Figure 14). The graph represents the cuff deflation portion of the SPP test cycle.
- The SPP test may take up to 5 minutes to complete.

4 – Stop Test

The SPP test can be discontinued at any time by selecting **4-Stop Test**, if needed.

5 – Save / User Override / Discard

The system software computes the SPP value and a diamond marks this location on the SPP graph (Figure 14). If the result provided by the system appears to be inaccurate, the user can select a different SPP result or discard the test completely.

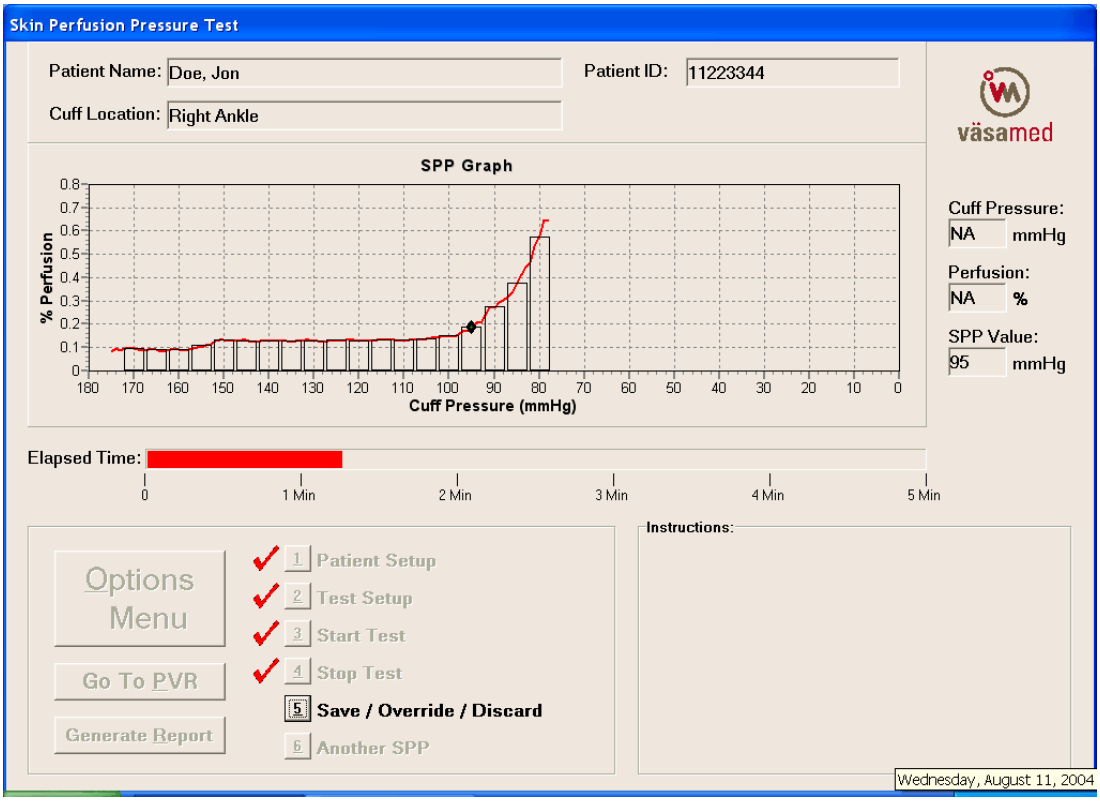


Figure 14. SPP Graph

1. Select **5-Save / Override / Discard** and make the appropriate selection.
   a. Select **Save Result** to save the test for inclusion on the report.
   b. Select **Override Result** to override the software-determined result. A vertical red line appears in the SPP graph (Figure 15).
      i. Use the mouse to move the red line to select a different SPP result.
      ii. Select the **Save SPP Value** button on the right side of the screen. The test data is saved.
   c. Select **Discard Test** to delete the result.

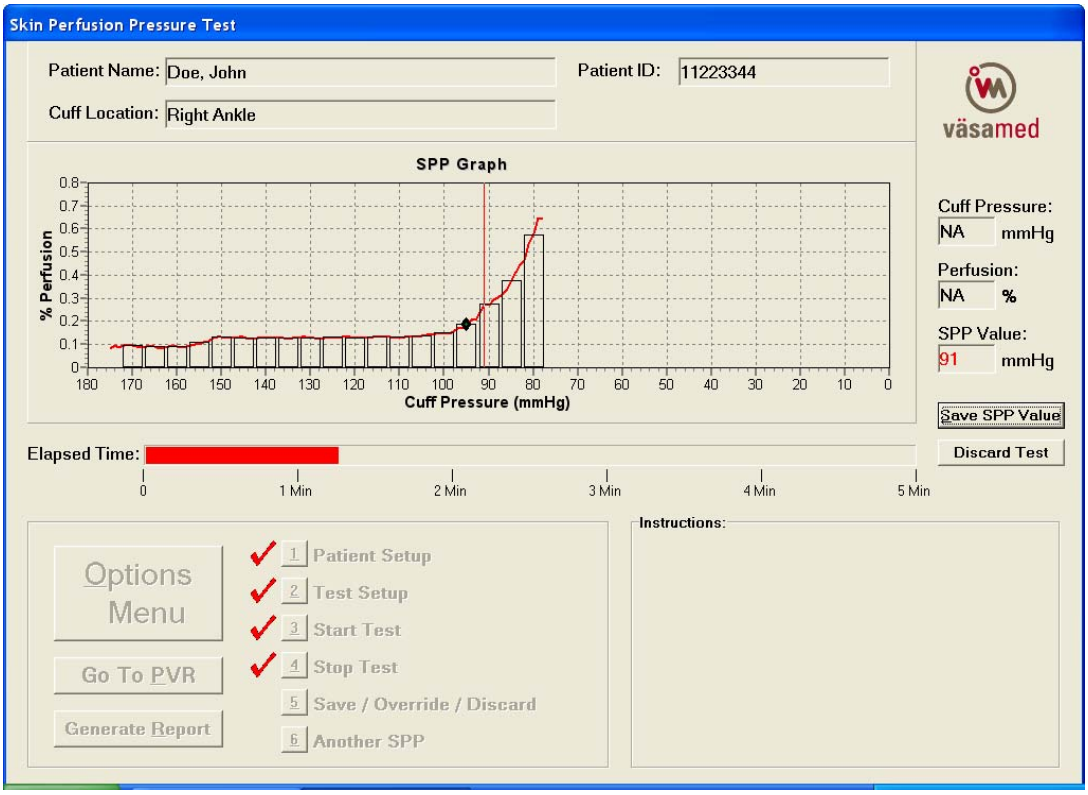


Figure 15. SPP Graph with User Override Red Line

Note

- The pressure cuff will deflate completely at the end of the test, if the system times out, or the user selects **Stop Test**.
- The SPP test may end before an acceptable test is completed if the user chooses to stop the test early, skin perfusion is not stopped, or an error occurs. If the test ends in an error, the test record is deleted.
- In cases where the software does not determine the SPP value and no diamond is displayed, the user may optionally observe the graph and select the pressure at which perfusion returns. Select **Yes** in the window if you wish to manually select an SPP result.

6 – Another SPP

Another SPP test can be performed by selecting **6-Another SPP.**

SPP Graph Interpretation

The SPP graph displays cuff pressure on the horizontal axis, decreasing from left to right and perfusion on the vertical axis with zero perfusion on the bottom and increasing upwards. The SPP graph horizontal axis is also segmented into pressure bars of 5-mmHg widths and having amplitude equal to the average of the perfusion across that same range. In current practice, SPP measurements are performed much the same as manual arterial segmental pressure measurements in the lower extremities. Skin Perfusion Pressure (SPP) is the term used to denote a specific cuff pressure wherein microcirculatory perfusion is first detected following a period of occlusion. At a high cuff pressure, one expects to see a perfusion that indicates the cessation of skin perfusion at that cuff pressure. This is referred to as a baseline reading. The baseline will sometimes decrease slightly during the initial portion of the deflation cycle since the disappearance of capillary flow does not occur immediately in response to the counter pressure of the cuff. The SPP value is the cuff pressure at which the perfusion reading increases above baseline and is followed by further increases at the next several pressure levels (Figure 15). This resumption of capillary perfusion is presented numerically and graphically on a display that shows the perfusion magnitude as a function of the cuff pressure.

The clinical question typically answered by an SPP investigation is whether a patient's skin circulation is sufficient for healing. SPP testing (as well as other physiological testing) does not evaluate other non-circulatory causes of healing failure, such as infection and nutritional deficit. However, insufficient perfusion by itself is useful in predicting healing failure since adequate perfusion is required in all successful wound healing scenarios regardless of concomitant pathology.

Patient movement or other artifact may occasionally produce an uneven baseline at high pressures. Short duration changes in the perfusion will not meet the criteria for automatic SPP determination by the software.

In cases where the software does not determine the SPP value, the user may optionally observe the graph and select the pressure at which perfusion returns.

At times, there will be no marked hyperemic response at low pressures and the SPP value cannot be determined by the software nor visually interpreted by the user. Use of a heating pad during the test may correct this problem but should be performed at the discretion of the physician.

SPP test results should be used in combination with other clinical information.

Pulse Volume Recording (PVR) Test

- **Warning: Do not kink or crush the LSA cable or Air Hose. A damaged cable or air hose can result in inaccurate values or an error message.**

- **Warning: To maintain proper ventilation and ensure proper cooling, place the DAS on a hard, flat surface with a minimum of 1-inch (2.5 cm) clearance around all sides of the DAS. Do not set the DAS on bedding.**

- **Caution: When performing an SPP measurement, do not place the LSA directly over a bone.**

- **Caution: Do not wrap the pressure cuff around the extremity too tightly. Blood flow may be restricted. Wrap the pressure cuff snugly, but not tightly, around the patient's extremity.**

- **Caution: The patient should be supine and lying completely still during SPP tests. Stay with the patient during the SPP test. Any type of patient movement, including talking, may result in incorrect or no results being displayed or cause the system to time out. Results may also be affected by movement of the Laser Sensor Assembly cable or the Air Hose.**

Performing a Pulse Volume Recording (PVR) Test

The Pulse Volume Recording (PVR) Test screen (Figure 16) is accessed by selecting **Go To PVR** from the Skin Perfusion Pressure Test Screen. A PVR test is performed by moving through the six steps listed on the PVR screen.

1 – Patient Setup
2 – Test Setup
3 – Start Test
4 – Stop Test
5 – Save Waveform / Discard Test
6 – Another PVR

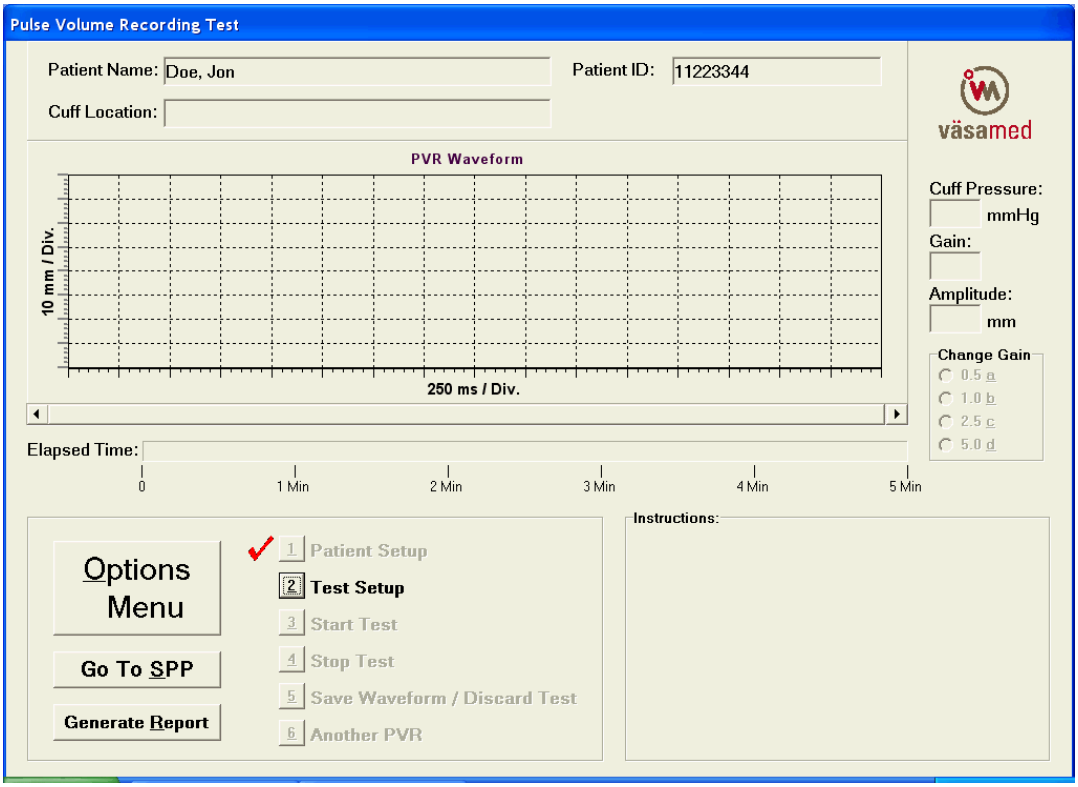


Figure 16. Pulse Volume Recording Test Screen

1 – Patient Setup

Before performing a (PVR) test, the patient should lie quietly for 10 minutes. Have the patient lie in a comfortable, supine position.

- If needed, select **Go To PVR** from the Skin Perfusion Pressure Test screen. The PVR test screen appears (Figure 16).
- If needed, select **1-Patient Setup**.

Note

- If an SPP test has been performed, patient setup is complete and does not need to be repeated. For complete instructions, see section **1 – Patient Setup** in the **Skin Perfusion Pressure (SPP) Test** section of this manual.

2 – Test Setup

1. Select **2-Test Setup**. The **PVR Test Setup** form appears (Figure 17).

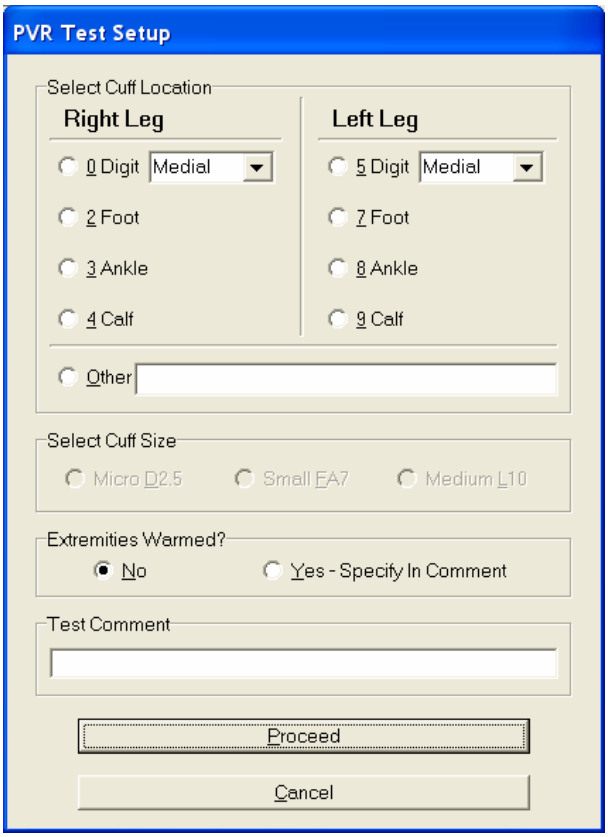


Figure 17. PVR Test Setup

2. Select the appropriate **Cuff Location**. Only one location can be selected.
3. A default cuff size based on the Cuff Location is automatically selected. Change the cuff size if needed.
4. Under **Extremities Warmed?**, **No** is automatically selected as the default. If a warming pad or other extraordinary means of providing warmth is used to warm the extremity, select **Yes** and explain in the **Test Comments** box.

Note

- Any patient position other than supine may affect the results.
- Use the appropriate size pressure cuff for the location that you are testing. Using a pressure cuff that is too large or small may affect the test.
- The patient should be at their comfortable/normal body temperature as should the extremity to be tested. If this is not the case, the patient should be covered with a blanket at the discretion of the physician.
- Use of a warming pad is not recommended but if its use is elected at the discretion of the physician, it should be noted during test setup.

5. Connect the pressure cuff to the Air Hose with the Luer connector.
6. Wrap the pressure cuff snugly around the patient's extremity.
7. Position the computer screen so the patient cannot see it.
8. When you are sure of your selections, select **Proceed**. The PVR Waveform screen appears.
9. Inform the patient that you are ready to start the test and that the cuff will apply pressure to the area being tested.

3 – Start Test

1. Select **3-(Start Test)** to begin the PVR test. The pressure cuff will automatically inflate and the PVR waveform will be displayed (Figure 18).

Note

- The system will maintain a constant pressure in the pressure cuff during the PVR test. **Cuff Pressure** is displayed during the PVR test. If the cuff loses pressure during the test, it will automatically be reinflated by the system.
- The gain of the graph can be adjusted. To increase the gain and size of the waveform, select a higher gain number. To decrease the gain and the size of the waveform, select a lower number.
- Amplitude, or the height of the PVR waveform, is displayed.

4 – Stop Test

1. The SPP test can be discontinued at any time by selecting **4-Stop Test**.
2. Use the mouse to move the gray horizontal bar below the PVR waveform graph to scroll through the waveform and select an artifact free four-second segment of the PVR waveform (Figure 18).

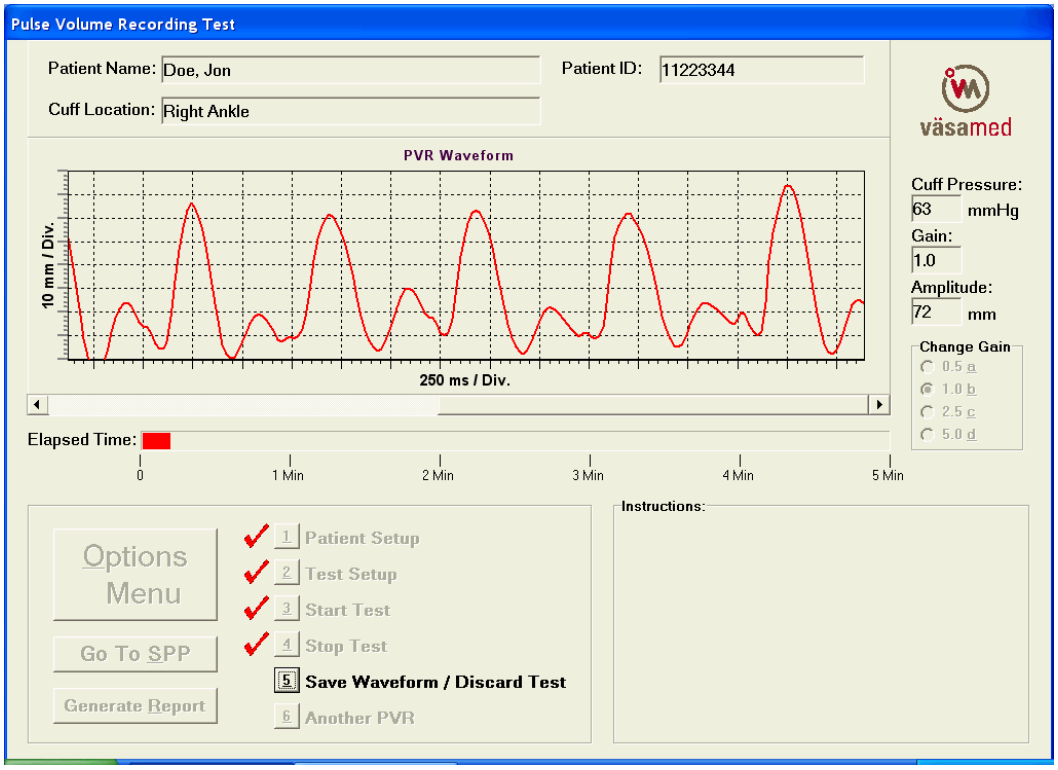


Figure 18. PVR Waveform Screen

5 – Save Waveform / Discard Test

1. Select **5-Save Waveform / Discard Test** and make the appropriate selection.
   a. Select **Save Selected PVR Waveform** to save the test for inclusion on the report.
   b. Select **Re-Select PVR Waveform** to select a different section of the PVR waveform.
      1. Use the mouse to move the gray horizontal bar below the PVR waveform graph to select a different segment of the PVR waveform.
      2. Select the **Select PVR** button on the right side of the screen.
      3. Select **Save Selected PVR Waveform** to save the test for inclusion on the report.
   c. Select **Discard Test** to delete the result.

Note

- Artifact caused by patient movement exhibits itself by destroying the cyclic nature of the waveform. In cases where the system automatically adjusts cuff pressure, a horizontal line is displayed to be easily distinguishable from the PVR waveform and physiologic events.

6 – Another PVR

Another PVR test can be performed by selecting **6-Another PVR**.

PVR Waveform Interpretation

Time is displayed on the horizontal axis of the PVR waveform. Millimeters are displayed on the vertical axis.

The contour of the PVR waveform may indicate severity of disease. In a healthy person, the contour will contain a steeply rising slope, fairly sharp peak, a reflected diastolic wave on the down slope, and the down slope should curve toward the baseline. In a mild to moderately obstructive contour, there may be a delay in the upstroke, a rounded peak, loss of the reflected wave, and a delayed down slope. In a severely obstructive contour, the waveform may have low amplitude and marked abnormalities, be associated with maximal vasodilatation and no response to hyperemia. An absence of pulsations may signify advanced arterial insufficiency often associated with rest pain, non-healing ulcers, and potential loss of limb or digit.

Reports

Reports include facility information, patient demographics, vascular history, test information, type of test (SPP or PVR), test location, and graphic results for up to eight individual SPP and eight individual PVR tests.

A report must be generated when the current patient session is complete and before testing another patient.

Report file names are created from the patient's ID number-year-month-day-hour-minute-second.qrp.

Sample file name: 123456-2004-03-02-14-22-11.qrp

Generate Report

To generate a report after testing a patient:

1. Select **Generate Report** from the SPP or PVR Test screen. The **Generate Report** screen is displayed (Figure 19).
2. Enter any **Report Comments**.
3. Select **Generate Report** from the pop-up window.

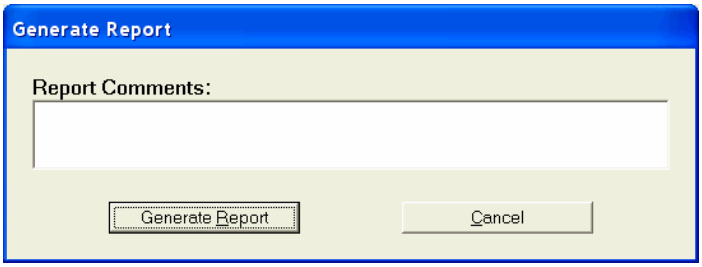


Figure 19. Generate Report Window

4. The report is displayed (Figure 20) and saved to disk.
5. Refer to Figure 21 for a description of the icons located at the top of the report screen.
6. Select the print icon to print the report.
7. Select the **Close** icon to close the report.

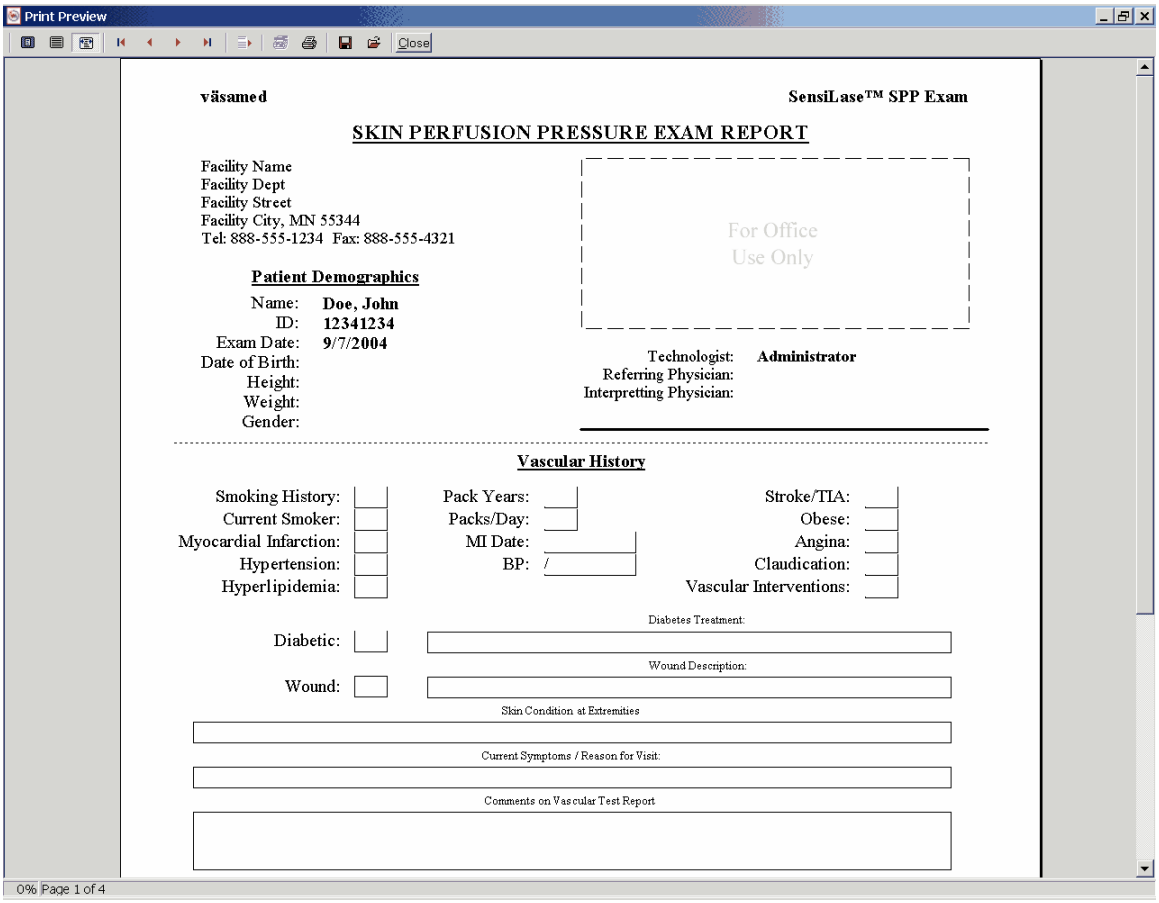


Figure 20. Report

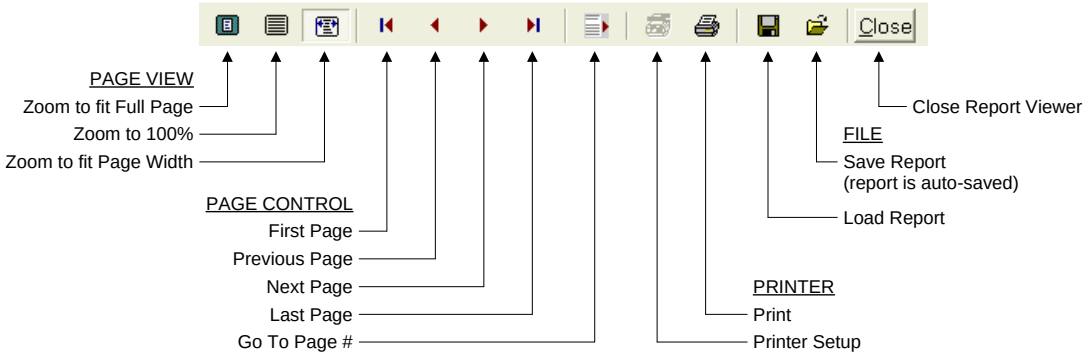


Figure 21. Report Icons

Previously generated reports may be viewed and printed.

1. Select **Options Menu** from the SPP or PVR Test screen.
2. Select **View / Print Reports**.
3. Follow the directions found in the **Options Menu – View / Print Reports** of this manual.

Options Menu

Select **Options Menu** from the SPP or PVR test screens to access the functions listed below. The **Options Menu** window is displayed (Figure 22).

- View / Print Reports
- About SPP View
- Operators Manual
- Logout
- Change User Password
- Administrative Tasks

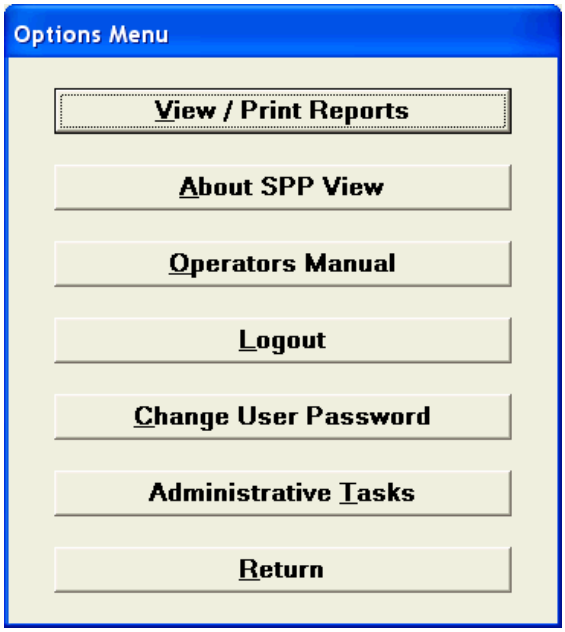


Figure 22. Options Menu Window

View and Print Reports

After selecting **View / Print Reports** from the **Options Menu**:

1. All reports for all patients, sorted by report file name, are displayed.
2. Select the appropriate patient's report.
3. Select **Open**. A print preview of the report is displayed (Figure 20).
4. The report can be viewed or the print icon may be selected.
5. Select the **Close** icon to close the report.

Report file names are created from the patient's ID number-year-month-day-hour-minute-second.qrp.

Sample file name: 123456-2004-03-02-14-22-11.qrp

About SPP View

Select **About SPP View** to display the software revision numbers and **väsamed** contact information.

Operators Manual

Select **Operators Manual** to display this SensiLase™ PAD 3000 Skin Perfusion Pressure System Operators Manual.

Logout

When a user is finished using the SensiLase System, the user should logout. To logout:

1. Select the **Options Menu**.
2. Select **Logout**.
3. The **Login** window is displayed allowing a different user to login.

Note

- Selecting **Exit** at the login screen closes the SPP View application.

Change Password

Each user may change their password. To change the password of the currently logged in user:

1. Select **Options Menu**.
2. Select **Change User Password**. The **Change User Password** window appears (Figure 23).
3. Enter a new password.
4. Reenter the new password.
5. Select **OK.**

Figure 23. Change User Password

Note

- Passwords can include numbers, letters or a combination of both.
- All users of the SensiLase System are responsible for controlling access to patient records within the system.
- The facility is responsible for determining how frequently individual passwords should be changed.

Administrative Tasks

Select **Options Menu** and then select **Administrative Tasks** to access the **Administrative Functions** window (Figure 24). Administrator tasks are only accessible to the user with the 'administrator' login. Administrative functions include:

- Add User
- Delete User
- Edit Facility Information

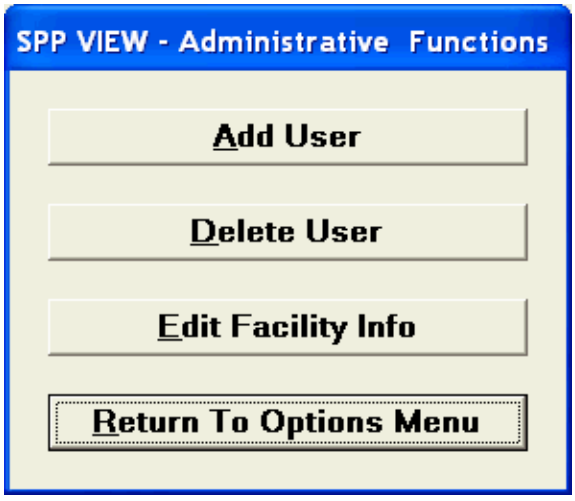


Figure 24. Administrative Functions Window

Add User

To add a new user:

1. Select **Administrative Tasks** from the **Options Menu**.
2. Select **Add User**. The **Add User** window appears (Figure 25).
3. Enter the user's login name.
4. Select **OK**. An information window appears stating the user was successfully added.
5. Select **OK**.

Note

- The new user creates their own password when they login for the first time.

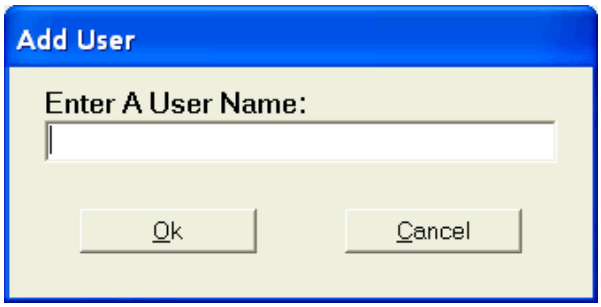


Figure 25. Add User Window

Delete User

To delete a user:

1. Select **Administrative Tasks** from the **Options Menu**.
2. Select **Delete User**. The **Delete User** window appears (Figure 26).
3. Use the drop down list to select the user to be deleted.
4. Select **OK** to delete user. An information window appears stating the user was successfully deleted.
5. Select **OK**.

Note

- The password of the user to be deleted does not need to be entered.

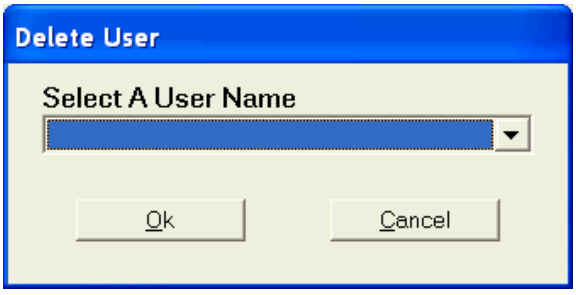


Figure 26. Delete User Window

Edit Facility Info

Facility (hospital or clinic) information includes the hospital or clinic name, address and telephone number. To enter or edit facility information:

1. Select **Administrative Tasks** from the **Options Menu**.
2. Select **Edit Facility Info**. The **Edit Facility Information** form appears (Figure 27).
3. Enter the appropriate information.
4. When the facility information is entered correctly, select **Save**.

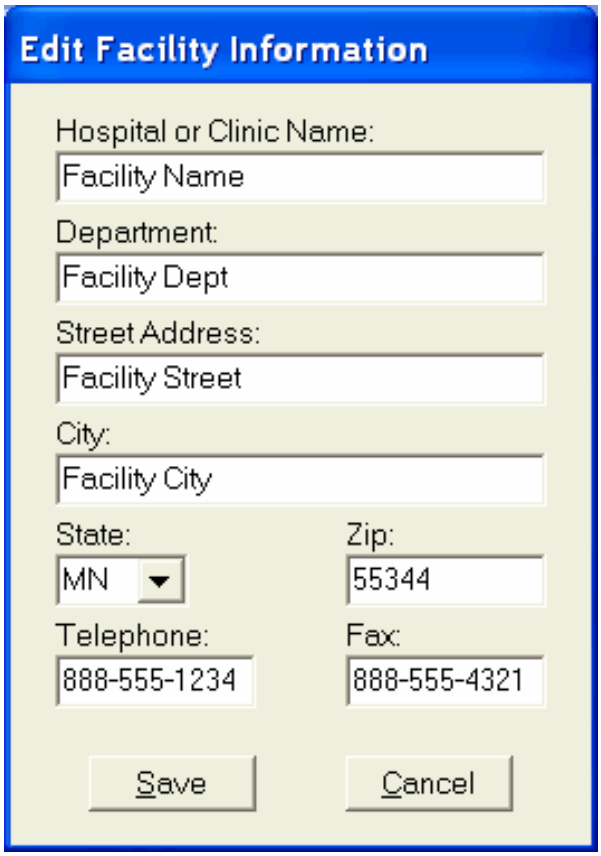


Figure 27. Edit Facility Information Form

Initial Administrative Login

For the initial administrative login after equipment setup:

1. Select **Administrator** from the **User Name** drop down list.
2. Enter the administrative **Password**. The default administrative password is **pad3000** and is case sensitive.
3. Select **Login**. The Skin Perfusion Pressure Test screen is displayed.
4. Change the administrative password. Follow the instructions under **Change Password** in this Operators Manual.

Printers

The SensiLase System PC can be connected to a variety of printers for report printing. Follow the original printer manufacturer's instructions for use.

Exit

1. Select Logout from the Options Menu.
2. Select **Exit**.
3. You may safely turn off the computer after logging out.

Technical Support

Help

An electronic version of this operator's manual may be accessed through the Options Menu.

Obtaining Technical Assistance

For technical information and assistance, contact **väsamed** at 1.800.695.2737 or your local **väsamed** representative.

If you call for technical assistance, make sure you have the DAS serial number available. It is found on the back of the DAS.

Maintenance

Returning SensiLase System Components

Contact **väsamed** at 1.800.695.2737 or your local väsamed representative for shipping instructions including a Returned Material Authorization (RMA) number. Unless otherwise instructed by **väsamed**, it is not necessary to return any accessory items with the SensiLase DAS. Pack the DAS in its original shipping carton. If the original carton is not available, use a suitable carton with appropriate packing material to protect during shipping. Use any shipping method that provides proof of delivery.

Service

Caution: The cover of the DAS should be removed only by authorized väsamed service personnel. There are no user-serviceable parts inside the DAS.

Caution: If service is necessary, contact väsamed or your local väsamed representative. No service should be attempted by anyone other than authorized personnel.

The SensiLase System requires no routine service or calibration. No periodic calibration is required.

Periodic Safety Checks

The following safety checks should be performed every 24 months by a qualified person who has adequate training, knowledge, and practical experience to perform these tests.

- Inspect the equipment for mechanical and functional damage.
- Look at the safety-relevant labels and inspect for legibility.
- Verify that the DAS functions properly as described in the operator's manual.
- Instrument electrical safety testing is recommended per the institution's recommended schedule.

Cleaning

Warning: Always dilute the cleaning solution according to the manufacturer's suggestion

Caution: Do not spray, pour, or spill any liquid on the SensiLase DAS, PC, accessories, connectors, switches, or openings in the DAS chassis.

Caution: Do not use wax-based cleaners, abrasives, solvents, including acetone, ketone or Betadine.

Caution: Ensure all components are clean before use.

After Patient Testing is Complete
Remove the cuff and LSA. Clean and disinfect the equipment and accessories according to your facility's approved procedures.

Suggested Method for Cleaning and Disinfecting the LSA, Cuffs, and Air Hose
Clean the LSA, cuffs, and air hose using a cloth dampened with 70% alcohol, 0.5% bleach, or water and detergent. Wipe the surfaces of each component.
Next, disinfect the LSA, cuffs, and air hose using 6% hydrogen peroxide solution, 10% bleach solution, or an ortho-Pthalaldehyde type (Cidex OPA) high level disinfectant prepared to the manufacturer's recommendations. Use a clean, soft, lint-free cloth to dry the surfaces.

Do **not**, under any circumstances, autoclave, or gamma sterilize the sensor.

Suggested Method for Cleaning and Disinfecting the DAS, PC, and Cables
Clean the DAS surfaces, PC surfaces, data port cable, AC power cord and power cable using a soft, lint-free cloth dampened with a commercial, nonabrasive detergent or cleaner. Lightly wipe the surfaces.
Next, disinfect the DAS surfaces, PC surfaces, data port cable, AC power cord, and power cable using a disposable germicidal wipe (PDI Super Sanicloth), or a soft, lint-free cloth saturated with a 10% solution of chlorine bleach and tap water. Use a clean, soft, lint-free cloth to dry the surfaces.

Disposal

Return system components to **väsamed** or dispose of per local regulations. Contact **väsamed** at 1.800.695.2737 or your local **väsamed** representative for shipping instructions including a Returned Material Authorization (RMA) number.

Error Messages

SPP Test Error Messages

Error Message	Condition	Corrective Action
No laser cable attached!	SPP test is started without the LSA cable attached.	Attach LSA cable and re-start test.
No laser signal! Contact väsamed (800-695-2737)	SPP test fails because DAS laser or laser drive circuit has failed.	Contact Väsamed technical service.
No valid baseline flow detected! Check the position and orientation of the laser.	SPP test fails because measurement indicates insufficient perfusion to start the test.	Confirm LSA is properly applied to skin surface. Check LSA connection to DAS. Clean LSA.
Maximum pressure reached! Ensure that the laser is positioned underneath the center of the pressure cuff.	SPP test fails because perfusion could not be reduced enough to continue.	Ensure LSA is positioned under center of pressure cuff.
Unable to control cuff pressure! Instruct the patient to lie still during the exam.	SPP test fails because cuff deflation could not be properly controlled.	Check cuff, air hose and connections for leaks. Ensure patient does not move during test.
SensiLase System Failure! Contact väsamed (800-695-2737)	SPP test failed because of a system failure.	Contact Väsamed technical service.
No SPP Value not found! Manually choose SPP value.	The software could not determine a SPP value from the SPP graph.	User selects SPP value or repeats the test
The test time limit is 5 minutes! Manually choose SPP value or repeat test.	SPP Test reached a five-minute maximum time limit.	User selects SPP value or repeats the test
An SPP data CRC error has occurred. The test has been aborted and should be repeated!	CRC errors have been encountered when communicating with the DAS.	Inspect data port cable and replace if damaged.

PVR Test Error Messages

Error Message	Condition	Corrective Action
PVR signal error! Contact väsamed (800-695-2737)	PVR measurement failure	Exit SPP VIEW, turn DAS OFF and then back ON, restart SPP VIEW. Contact Väsamed technical service if error recurs.
SensiLase System Failure! Contact väsamed	PVR test failed because of a system failure.	Contact Väsamed technical service.

(800-695-2737)		

"A PVR data CRC error has occurred. The test has been aborted and should be repeated!"	CRC errors have been encountered when communicating with the DAS.	Inspect data port cable and replace if damaged.

SensiLase System Failure Messages

Error Message	Condition	Corrective Action
DAS - is locked	DAS communication interface is locked	Logout and Exit SPP VIEW. Restart SPP VIEW.
DAS - laser temperature measurement error	DAS laser temperature measurement has failed	Contact Väsamed technical service.
DAS - laser heater error	DAS laser heater has failed	Contact Väsamed technical service.
DAS - laser current error	DAS laser current control has failed	Contact Väsamed technical service.
DAS - detector temperature measurement error	DAS detector temperature measurement has failed	Contact Väsamed technical service.
DAS - detector heater error	DAS detector heater has failed	Contact Väsamed technical service.
DAS - power supply failure (5v)	DAS 5 volt power supply has failed.	Contact Väsamed technical service.
DAS - power supply failure (12v)	DAS 12 volt power supply has failed.	Contact Väsamed technical service.
DAS - maximum cuff pressure exceeded	DAS maximum cuff pressure has been exceeded	Contact Väsamed technical service.
DAS - invalid hardware type	DAS an invalid hardware type has been detected	Contact Väsamed technical service.
DAS - demo file not found	DAS unable to find the demo file	Contact Väsamed technical service.
DAS - analog I/O task error	DAS an analog I/O task error has occurred	Contact Väsamed technical service.
DAS - disk space is low	DAS internal storage is low; DAS will automatically reduce storage needs.	No user intervention is required.
DAS - disk space is very low	DAS internal storage is very low; DAS will automatically reduce storage needs.	No user intervention is required.
DAS - cannot open log file	DAS has a corrupt or missing log file.	Contact Väsamed technical service.
DAS - cannot open configuration file	DAS has a corrupt or missing configuration file.	Contact Väsamed technical service.

Note

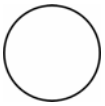
- The green power indicator on the DAS front panel blinks when the SensiLase System is first turned on and SPP view has not yet communicated with the DAS or when an error occurs.
- For all errors, contact **väsamed** Technical Service at 1.800.695.2737 if the error cannot be resolved by the corrective actions noted above.

Specifications

Item	Specification
Performance	
Perfusion Measurement Range	0.00% to 10.00%
Cuff Pressure (mean)	0-250 mmHg
PVR Amplitude	Max 80 mm display, 1 to 30 Hz frequency response
Electrical	
Power Requirements	100/120V 50/60 HZ 4.4 A
Fuse	5A/250V, 3AG, slow blow
AC Power Cord	1250 Watts 10A-125V low leakage, hospital grade, 8 ft.
Laser	
Power exiting LSA	2.35 milliwatts, typical 2.55 milliwatts, maximum
Wavelength	785 nm
Environmental (DAS)	
Operating Temperature	5° C to 40° C (41° F to 104° F)
Altitude/Barometric Pressure	50 kPa to 106 kPa -1,254 feet to 18,289 feet -382 m to 5574 m
Relative Humidity	15% to 95%, non-condensing
Transport and Storage Temperature	-20° C to 60° C (-4° F to 140° F)
Physical Characteristics (DAS)	
Weight	4.5 kgs (10.0 lbs)
Dimensions of the DAS (WLH)	33 x 32 x 10 cm (13 x 12.5 x 4 in)
Compliance	
Safety	IEC 60601-1
Degree of protection against electrical shock	Class I – Power source Type BF – Applied part
Electromagnetic compatibility	IEC 60601-1-2
Laser safety	Complies with FDA performance standards for laser products except for deviations pursuant to Laser Notice No. 50, dated July 26, 2001. Class I per 21 Code of Federal Regulations (CFR)

	1040.10 Class 1M per IEC 60825-1, Edition 1.2 (2001-08)
Resistance to liquid ingress	IPX0 per IEC 60529 (not protected)
Degree of safety in presence of a flammable anesthetic	Not suitable
Mode of operation	Continuous
Personal computer	IEC 60950-1

Symbols

Symbol	Description
	Attention, consult accompanying documents.
	Type BF applied part.
	Power ON.
	Power OFF.

Technical Description

Fuse Replacement

Replace fuses only with type described in Specifications.

Perform the following steps to replace fuses.

1. Switch the DAS AC Power Switch to OFF position (○).
2. Disconnect the AC Power Cord from the AC Power Outlet.
3. Disconnect the AC Power Cord from the Power Entry Module.
4. Open the Fuse Holder door.
5. Remove the Fuse Holder.
6. Remove and replace fuses.
7. Install the Fuse Holder. Ensure the fuse holder is properly oriented.
8. Close the Fuse Holder door.
9. Reconnect the AC Power Cord to the Power Entry Module.
10. Connect the AC Power Cord from the AC Power Outlet.
11. Switch the DAS AC Power Switch to the ON position.

Power Cord Replacement

Replace the AC power cord immediately upon the first sign of chemical or physical damage. Replace the AC power cord only with type described in Specifications.

Circuit Diagrams & Component Parts List

väsamed will make available, on request, circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist authorized service personnel to repair those parts of the SensiLase System that are designated by **väsamed** as repairable by authorized service personnel.

Network / Data Coupling

Connection of the SensiLase System, including the PC, to other equipment, could result in previously unidentified risks to patients, operators or third parties. The organization responsible should identify, analyze, evaluate, and control these risks. Subsequent changes to the network or data coupling configuration could introduce new risks and require additional analysis. Changes to the network / data coupling configuration include:

- changes in network / data coupling configuration of SensiLase System
- connection of additional items to the SensiLase System
- disconnecting items from the SensiLase System
- update of equipment connected to the SensiLase System
- upgrade of equipment connected to the SensiLase System

Mains Isolation Switch

The mains isolation switch is located on the rear of the DAS and controls power to the DAS and to the power output port.

Hazardous Substances and Materials

Improper disposal of the portable computer battery pack can cause an environmental hazard. Dispose of the old battery pack by following local guidelines for disposal of batteries.

Customer Supplied Computer Minimum Requirements

Caution: väsamed is not responsible if the DAS is connected to a computer that does not comply with medical safety regulations. The system of DAS and computer must have a leakage current < 0.1 mA and be compatible with applicable medical safety regulations.

The minimum requirements for a customer supplied computer are:

- Must comply to IEC 60950-1 "Information technology equipment - Safety - Part 1: General requirements"
- Mouse or integral mouse pad
- Hard disk capacity: 5 gigabytes
- Video: 1024x768
- OS: Microsoft Windows XP
- CPU: Intel Pentium or Intel Celeron with 2 GHz processor.
- RAM: 256MB
- RS232 port*, or
- USB port*
- SensiLase PC Software

Computer Graphic Speed

Important Note: The graphic speed of some computers is incapable of displaying a PVR waveform without a lag in waveform display. A computer with insufficient graphic speed should not be used with the DAS.

väsamed-Supplied Software*

A customer supplied computer requires installation of SensiLase PC software.

Option A: United States English SensiLase Systems

- SPP VIEW Software Installation Disk. This contains the SensiLase PC Software Installation Procedure, Adobe Acrobat Viewer and the Operator's Manual. This software is labeled "SPP VIEW Software Installation Disk".
- SensiLase United States English Systems require one (1) USB port. These systems will be shipped with a cable and driver software. The driver software is labeled CD#2 and is a USB to RS232 Adapter and Driver.

Option B: International English SensiLase Systems

- SPP VIEW Software Installation Disk. This contains the SensiLase PC Software Installation Procedure, Adobe Acrobat Viewer and the Operator's Manual. This software is labeled "SPP VIEW Software Installation Disk".
- SensiLase International English Systems can support two types of communication interface.
    - Type 1. RS2332 port. This is recommended. These systems will be shipped with a cable only since no driver software is required.
    - Type 2. USB port. This is not a preferred configuration. These systems will be shipped with a cable and driver software. The driver software is on a floppy disk packaged with the USB to RS232 Adapter and Driver.

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